

S/N 10/562,866

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bror Morein et al.

Examiner: Nina Archie

Serial No.: 10/562,866

Group Art Unit: 1645

Filed: May 16, 2006

Docket: 1876.052US1

Title: Quil a fraction with low toxicity and use thereof

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Karin Lovgren Bengtsson, declare and say as follows:

1. I am a co-inventor of the subject matter claimed in the above-identified U.S. patent application, U.S. application Serial No. 10/562,866, filed on May 16, 2006.
2. I obtained a B.Sc. in Biochemistry from Uppsala University in Uppsala, Sweden in 1981, after which I obtained a Ph.D. in Vaccinology from the University of Agricultural Sciences, Faculty of Veterinary Medicine, Department of Veterinary Microbiology, section of virology in Uppsala, Sweden in 1987. Additionally, in 1987 I was a researcher at the National Veterinary Institute in Uppsala, Sweden. In 1992 I was a Research Associate at the University of Agricultural Sciences, Department of Veterinary Microbiology section of Virology, in Uppsala, Sweden and became an Associate Professor in 1995 at the University of Agricultural Sciences, Faculty of Veterinary Medicine, Department of Veterinary Microbiology, section of Virology in Uppsala, Sweden. In 1998 I became the Chief of Operations for Isconova AB in Uppsala, Sweden and currently I am the CSO of Isconova AB in Uppsala, Sweden. From 2000 to 2004 I was also a senior lecturer for the University of Agricultural Sciences, Department of Veterinary Microbiology in Uppsala, Sweden.
3. I have read and am familiar with the Office Action dated February 2, 2009 with respect to the above-identified application, and make this Declaration in support of the patentability of the claims of U.S. application Serial No. 10/562,866.

4. In the Office Action mailed February 2, 2009, the Examiner rejected claims 1-2, 4-9 and 14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Friede et al. (U.S. Patent No. 6,558,670).

5. Applicant provides herewith Attachment 1 titled "Intranasal administration of PR8 micelles," which provides data from an assay in which the Applicant tested fraction A and C from Quil A in an intranasal administration of fraction A and C of Quil A in free form. It is evident from the results that Fraction A of Quil A does not improve the IgA titre (columns 2, 3 and 4 of the figure present in Attachment 1) after intranasal administration. This example demonstrates and confirms the intranasal adjuvant effect of Fraction-C, which comprises fraction QS 21 and other saponins. However, no such effect is shown with Fraction-A. Further, fraction A of Quil A is not haemolytic. This is also evident from Cox (WO 96/11711). Thus, saponin fraction A of Quil A, which must be present in Applicant's invention, has another effect than saponin QS 21 (part of fraction C) disclosed, preferred and tested by Friede et al.

6. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Dated: August 6, 2009

By: Karin Lovgren Bengtsson
Karin Lovgren Bengtsson

Attachment 1

Intranasal administration of PR8 micellers (3 ug) with and without addition of Fraction-A or Fraction-C i free form

| | |
|----------|------------------------------|
| 0 | 3 ug PR8 alone |
| 0,025% A | 3 ug PR8 + 0,025% Fraction-A |
| 0,050% A | 3 ug PR8 + 0,050% Fraction-A |
| 0,100 %A | 3 ug PR8 + 0,100% Fraction-A |
| 0,025% C | 3 ug PR8 + 0,025% Fraction-C |
| 0,050% C | 3 ug PR8 + 0,050% Fraction-C |
| 0,100 %C | 3 ug PR8 + 0,100% Fraction-C |

